MEMORANDUM

Re: Research quality control procedures at MPs department

Respondent: Albert Gjedde

The Department of Neuroscience and Pharmacology has established no legally binding procedures for research documentation by its researchers, except when collaborations require that GLP rules be observed. Indeed, no such formal rules exist anywhere in Denmark, except when GLP rules apply. This is clearly a weakness which is further compounded by the digital nature of current information technology.

However, the Department expects researchers to follow universally accepted procedures that require the researchers to maintain accurate and complete records that can be reviewed and transmitted to other researchers that have a legitimate reason to examine the details of the day-to-day activities of specific projects. The records can take the form of protocols that are completed daily and signed and dated by the individuals performing the practical steps of the research, including entry of results in the original form or reference to protected computerized files where these results can be retrieved. It is assumed that researchers are taught to adopt these procedures during their research training. In the final analysis, the individual researcher and author of publications is personally responsible for the accuracy of the data presented.

The question of the burden of proof is important here. In normal legal exchange, the burden of proof is on the accuser, except in specific cases of sexual harassment where some institutions in the US have inverted the principle. In scientific discourse, however, the principle clearly is the inverse: Whoever makes a scientific claim is required to establish the foundations on which the claim is based. If this is not possible, through negligence, misfortune, disease or death, the claim generally is rejected until it can be retested.
If it cannot in principle be tested or retested, it is not considered a scientifically valid claim. Yet, it is clear that such failure to provide the necessary bases for a claim does not pari passu constitute a proof of scientific misconduct.

One issue is how electronic records in the form of images and numbers can be protected against loss, disintegration and improper manipulation, particularly in the face of requirements by publishers that relate to the standards of images and data tables. Electronic resources now exist, such as LabArchives, where subsequent versions of images and numbers can be stored permanently, without the option of erasure. These sites are commercial, however, and it is unclear how permanent the storage really is. There are examples in Denmark of private clinics that deleted all records upon closure of the clinic, allegedly to protect patient privacy.